

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Not for submission under 37 CFR 1.99)</i>	Application Number	10624389
	Filing Date	2003-07-22
	First Named Inventor	Mark C. Estes
	Art Unit	3763
	Examiner Name	Matthew F. DeSanto
	Attorney Docket Number	PF01022US

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	2	6641533		2003-11-04	Causey, III et al.	
	3	6654625		2003-11-25	Say et al.	
	4	6671554		2003-12-30	Gibson et al.	
	5	6676816		2004-01-13	Mao et al.	
	6	6689091		2004-02-10	Bui et al.	
	7	6689265		2004-02-10	Heller et al.	
	8	6733471		2004-05-11	Ericson et al.	

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	9	6746582		2004-06-08	Heller et al.	
	10	6749740		2004-06-15	Liamos et al.	
	11	6809653		2004-10-26	Mann et al.	
	12	6872200		2005-03-29	Mann et al.	
	13	6881551		2005-04-19	Heller et al.	
	14	6893545		2005-05-17	Gotoh et al.	
	15	6916159		2005-07-12	Rush et al.	
	16	6932584		2005-08-23	Gray et al.	
	17	6932894		2005-08-23	Mao et al.	
	18	6936029		2005-08-30	Mann et al.	
	19	6942518		2005-09-13	Liamos et al.	

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	20	6945760		2005-09-20	Gray et al.	
	21	6979326		2005-12-27	Mann et al.	
	22	6997920		2006-02-14	Mann et al.	
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	1	20020082665	A1	2002-06-27	Haller et al.	
	2	20020161288	A1	2002-10-31	Shin et al.	
	3	20030078560	A1	2003-04-24	Miller et al.	
	4	20030088166	A1	2003-05-08	Say et al.	
	5	20030152823	A1	2003-08-14	Heller et al.	

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	6	20030168338	A1	2003-09-11	Liamos et al.	
	7	20030176183	A1	2003-09-18	Drucker et al.	
	8	20030188427	A1	2003-10-09	Say et al.	
	9	20030199744	A1	2003-10-23	Buse et al.	
	10	20030220552	A1	2003-11-27	Reghabi et al.	
	11	20040061232	A1	2004-04-01	Shah et al.	
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	13	20040064156	A1	2004-04-01	Shah et al.	
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	15	20040074785	A1	2004-04-22	Holker et al.	
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	17	20040111017	A1	2004-06-10	Say et al.	
	18	20050214585	A1	2005-09-29	Bernatz et al.	

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	1	4329229	DE	A1	1995-03-09			<input type="checkbox"/>
	2	0098592	EP	A2	1984-01-18			<input type="checkbox"/>
	3	0680727	EP	A1	1995-11-08			<input type="checkbox"/>
	4	0806738	EP	A1	1997-11-12			<input type="checkbox"/>
	5	0880936	EP	A2	1998-12-02			<input type="checkbox"/>
	6	1048264	EP	A1	2000-11-02			<input type="checkbox"/>
	7	1338295	EP	A1	2003-08-27			<input type="checkbox"/>

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	8	2218831	GB	A	1989-11-22			<input type="checkbox"/>
	9	9528878	WO	A1	1995-11-02			<input type="checkbox"/>
	10	9620745	WO	A1	1996-07-11			<input type="checkbox"/>
	11	9636389	WO	A1	1996-11-21			<input type="checkbox"/>
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	15	9800056	WO	A1	1998-01-08			<input type="checkbox"/>
	16	9820439	WO	A1	1998-05-14			<input type="checkbox"/>
	17	9824358	WO	A2	1998-06-11			<input type="checkbox"/>
	18	9842407	WO	A1	1998-10-01			<input type="checkbox"/>

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	19	9849659	WO	A2	1998-11-05			<input type="checkbox"/>
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	21	9859487	WO	A1	1998-12-30			<input type="checkbox"/>
	22	9908183	WO	A1	1999-02-18			<input type="checkbox"/>
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	24	9918532	WO	A1	1999-04-15			<input type="checkbox"/>
	25	9922236	WO	A1	1999-05-06			<input type="checkbox"/>
	26	9945375	WO	A1	1999-09-10			<input type="checkbox"/>
	27	9945387	WO	A2	1999-09-10			<input type="checkbox"/>
	28	9956613	WO	A1	1999-11-11			<input type="checkbox"/>
	29	0019887	WO	A1	2000-04-13			<input type="checkbox"/>

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	30	0047109	WO	A1	2000-08-17			<input type="checkbox"/>
	31	0078210	WO	A1	2000-12-28			<input type="checkbox"/>
	32	0128416	WO	A1	2001-04-26			<input type="checkbox"/>
	33	0128495	WO	A2	2001-04-26			<input type="checkbox"/>
	34	0139089	WO	A1	2001-05-31			<input type="checkbox"/>
	35	0152718	WO	A2	2001-07-26			<input type="checkbox"/>
	36	0152727	WO	A1	2001-07-26			<input type="checkbox"/>
	37	0156454	WO	A2	2001-08-09			<input type="checkbox"/>
	38	02058537	WO	A2	2002-08-01			<input type="checkbox"/>

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	1	Bode, BW et al., "Reduction in Severe Hypoglycemia with Long-Term Continuous Subcutaneous Insulin Infusion in Type I Diabetes", Diabetes Care, Vol. 19, No. 4, 324-327 (1996)	<input type="checkbox"/>
	2	Boland, E, Teens Pumping it Up! Insulin Pump Therapy Guide for Adolescents, 2nd Edition (1998)	<input type="checkbox"/>
	3	Brackenridge, BP, "Carbohydrate Gram Counting: A Key to Accurate Mealtime Boluses in Intensive Diabetes Therapy", Practical Diabetology, Vol. 11, No. 2, Pages 22-28 (1992)	<input type="checkbox"/>
	4	Brackenridge, BP et al., Counting Carbohydrates: How to Zero in on Good Control using the MiniMed insulin pump, MiniMed Technologies Inc. (1995)	<input type="checkbox"/>
	5	Farkas-Hirsch, R et al. "Continuous Subcutaneous Insulin Infusion: A Review of the Past and Its Implementation for the Future", Diabetes Spectrum From Research to Practice, Vol. 7, No. 2, Pages 80-84, 136-138 (1994)	<input type="checkbox"/>
	6	Hirsch, IB et al., "Intensive Insulin Therapy for Treatment of Type I Diabetes", Diabetes Care, Vol. 13, No. 12, Pages 1265-1283 (1990)	<input type="checkbox"/>
	7	Kulkarni, K et al., "Carbohydrate Counting: A Primer for Insulin Pump Users to Zero in on Good Control", MiniMed Inc. (1999)	<input type="checkbox"/>
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	9	Reed, J, "Living with Diabetes", Voice of the Diabetic, Vol. 11, No. 3, Pages 1-38 (1996)	<input type="checkbox"/>
	10	Skyler, JS, "Continuous Subcutaneous Insulin Infusion [CSII] With External Devices: Current Status", Update in Drug Delivery Systems, Futura Publishing Company, Chapter 13, Pages 163-183 (1989)	<input type="checkbox"/>
	11	Skyler, JS et al., The Insulin Pump Therapy Book: Insights from the Experts, MiniMed Technologies (1995)	<input type="checkbox"/>

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12	Strowig, SM, "Initiation and Management of Insulin Pump Therapy", The Diabetes Educator, Vol. 19, No. 1, Pages 50-60 (1993)	<input type="checkbox"/>
13	Walsh, J et al., Pumping Insulin: The Art of Using an Insulin Pump, Published by MiniMed Technologies (1989)	<input type="checkbox"/>
14	"Insulin Infusion Pump Therapy," Pages 66-78, Intensive Diabetes Management, 1995	<input type="checkbox"/>
15	MiniMed Dosage Calculator Initial Meal Bolus Guidelines/MiniMed Dosage Calculator Intial Basal Rate Guidelines Percentage Method, MiniMed, 4 pages, 1994	<input type="checkbox"/>
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17	MiniMed Now I Can Correction Bolus Calculator/MiniMed Now I Can Meal Bolus Calculator (07/2000)	<input type="checkbox"/>
18	MiniMed Now I Can brochure (09/2000)	<input type="checkbox"/>
19	MiniMed Now I Can MiniMed Diabetes Management packet (9/2000)	<input type="checkbox"/>
20	Medtronic MiniMed Meal Bolus Calculator and Correction Bolus Calculator; International Version (02/2002)	<input type="checkbox"/>
21	User's Guide for 508 Insulin Pump, Medtronic MiniMed (9/2001)	<input type="checkbox"/>
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	23	Abel, P. et al., "Experience with an implantable glucose sensor as a prerequisite of an artificial beta cell", <i>Biomed. Biochim. Acta</i> 43 (1984) 5, pp. 577-584	<input type="checkbox"/>
	24	Kawamori, R. et al., "Perfect Normalization of Excessive Glucagon Responses to Intravenous Arginine in Human Diabetes Mellitus with the Artificial Beta-Cell", <i>Rapid Publication from Diabetes</i> , Vol. 29, (September 1980), pp. 762-765	<input type="checkbox"/>
	25	Mastrototaro, John J. et al., "An Electroenzymatic Sensor Capable of 72 Hour Continuous Monitoring of Subcutaneous Glucose", Presentation given at the 14th International Diabetes Federation Congress in Washington, D.C., (June 23-28, 1991), 19 pages	<input type="checkbox"/>
	26	McKean, B., et al., "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors", <i>IEEE Transactions on Biomedical Engineering</i> , (July 1988), Vol. 35, No. 7, pp. 526-532	<input type="checkbox"/>
	27	Monroe, D. et al., "Novel implantable glucose sensors", <i>ACL</i> , (December 1989), pp. 8-16	<input type="checkbox"/>
	28	Nishida, K. et al., "Clinical applications of the wearable artificial endocrine pancreas with the newly designed needle-type glucose sensor", <i>(Elsevier Science B.V.)</i> , (1994), pp. 353-358	<input type="checkbox"/>
	29	Shichiri, M. et al., "An artificial endocrine pancreas – problems awaiting solution for long-term clinical applications of a glucose sensor", <i>Frontiers Med. Biol. Engng</i> , (VSP), (1991), Vol. 3., No. 4, pp. 283-292	<input type="checkbox"/>
	30	Shichiri, M. et al., "Wearable Artificial Endocrine Pancreas with Needle-Type Glucose Sensor", <i>The Lancet</i> , (November 20, 1982), pp. 1129-1131	<input type="checkbox"/>
	31	Shichiri, M. et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor: A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals", <i>Diabetes Care</i> , (May-June 1986), Vol. 9, No. 3, pp. 298-301	<input type="checkbox"/>
	32	Shichiri, M. et al., "Normalization of the Paradoxical Secretion of Glucagon in Diabetics Who Were Controlled by the Artificial Beta Cell", <i>Diabetes</i> , (April 1979), Vol., 28, pp. 272-275	<input type="checkbox"/>
	33	Shichiri, M. et al., "Closed-Loop Glycemic Control with a Wearable Artificial Endocrine Pancreas Variations in Daily Insulin Requirements to Glycemic Response", <i>Rapid Publication from Diabetes</i> , Vol. 33, (December 1984), pp. 1200-1202	<input type="checkbox"/>

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34	Shichiri, M. et al., "A Needle-Type Glucose Sensor – A Valuable Tool Not Only for a Self-Blood Glucose Monitoring But for a Wearable Artificial Pancreas-", Life Support Systems, Proceedings XI Annual Meeting ESAO Alpbash-Innsbruck Austria, (September 1984), Vol. 2, Supplement 1, pp. 7-9	<input type="checkbox"/>
35	Shichiri, M. et al., "The Wearable Artificial Endocrine Pancreas with a Needle-Type Glucose Sensor: Perfect Glycemic Control in Ambulatory Diabetics", Acta Paediatr Jpn 26, (1984), pp. 359-370	<input type="checkbox"/>
36	Shichiri, M. et al., "Glycaemic Control in Pancreatectomized Dogs with a Wearable Artificial Endocrine Pancreas", Diabetologia 24, (1983), pp. 179-184	<input type="checkbox"/>
37	Shults, M.C. et al., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors", IEEE Transactions on Biomedical Engineering, (1994), Vol. 41, No. 10, pp. 937-942	<input type="checkbox"/>
38	Wang, J. et al., "Needle-Type Dual Microsensor for the Simultaneous Monitoring of Glucose and Insulin", Analytical Chemistry, (February 15, 2001), Vol. 73, No. 4, pp. 844-847	<input type="checkbox"/>
39	Furler, SM et al., "Development and testing of a simple algorithm for a glucose clamp," Medical & Biological Engineering & Computing (July 1986 UK) (vol. 24, no. 4, pp.365-370, XP0022589180, ISSN: 0140-0118, page 367, left hand column, lines 23-29)	<input type="checkbox"/>
40	International Search Report for International Application No. PCT/US03/22862 filed 23 July 2003	<input type="checkbox"/>

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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.
 Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
 None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Vivian S. Shin/	Date (YYYY-MM-DD)	2007-06-12
Name/Print	Vivian S. Shin	Registration Number	43,919

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